User Manual

FUSSEN

F100

Digital intraoral x-ray imaging system

Version 1.0

CE 0123

About this Manual

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Statement

The User Guide for F100 includes information on the devices as well as their usage. We recommend that you thoroughly familiarize yourself with this Guide in order to make the most effective use of your system. User's operation failing to comply with this manual may result in malfunction or accident for which Fussen Technology Co., Ltd. (hereinafter called Fussen) can not be held liable.

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Responsibility of the Manufacturer

Fussen only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by Fussen, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, Fussen may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which Fussen may define as user serviceable.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A NOTE provides useful information regarding a function or a procedure.

Table of Contents

1 Safety Guidance

This chapter provides important safety information related to the use of Digital intraoral x-ray imaging system.

1.1 Intended Use

The system is used by dentists and other legally qualified professionals for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures in hospitals or clinics. The system is intended for adult patients，but paediatric and pregnant women with caution.

1.2 Contraindications

None known.

1.3 Warnings and Cautions

In order to use the system safely and effectively, Please read this manual carefully and be familiar with the proper operation method of ORFC Software and sensor before starting to use the device, paying particular attention to warnings, especially safety warnings.

NOTE:

1. This system is not intended for home use.
2. The pictures and windows in this manual are for reference only.

1.3.1 Safety Warnings

WARNING

1. Failure to follow the safety instructions for operating the instrument and system could endanger the patient. The manufacturer accepts no liability for damages resulting from improper use.
2. System installation shall be in accordance with the requirements of IEC 60601-1, the Standard for Safety Requirements of Medical Electrical Systems .

3. Only qualified and authorized personnel may operate this equipment observing all laws and regulations concerning radiation protection
4. This system is not intended for treatment.
5. This equipment must only be used in rooms or areas that comply with all applicable laws and recommendations concerning electrical safety in rooms used for medical purposes.
6. The diagnosis and examination function of the system should be integrated with clinical situation of patients, and the diagnostic results are only for physician's reference.
7. EXPLOSION HAZARD-Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
8. The device is not waterproof. Do not use it in locations where water or any liquid leakage may occur.
9. Do not use any fluid onto the system surface, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.
10. Do not spray cleansers on the system, as this may force cleaning fluid into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.
11. If the device breaks down, please shut down the machine immediately and contact Fussen or authorized representatives
12. Equipment connected to the sensor and located in the patient zone must be powered from a medically-isolated power source or must be a medically-isolated device. Equipment powered from a non-isolated source can cause your system to exceed leakage current limits. Enclosure leakage current created by an accessory or device connected to a non-isolated outlet may add to the enclosure leakage current of the imaging system
13. When more than one medical device is connected to the patient, leakage current of the devices is summed together. Take caution.
14. SHOCK HAZARD-Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.
15. SHOCK HAZARD - Don't connect non-medical electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.
16. SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlets supplying the system.
17. Do not exceed the maximum permitted load when using multiple portable socket-outlets to

supply the system.

18. Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer. And the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.
19. Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously.
20. To avoid the possibility of electrostatic shock and damage to the system, avoid using aerosol spray cleansers on the monitor screens.
21. The computer and any other associated equipment (like external printer) shall be placed outside the patient's environment (i.e.: more than 2 meters away from the chair). The operator shall not access the patient and such devices at the same time.
22. If the liquid crystal material leaks from the panel, it should be kept away from the eye or mouth. In case of contact with hands, skin or clothes, it has to be washed away thoroughly with soap.
23. Do not move the main unit or the monitor while working.
24. Only accessories supplied or recommended by the manufacturer can be connected to the system.
25. **EMI Limitations**

Possible EMI sources should be identified before the unit is installed.

Electrical and electronic equipment may produce EMI unintentionally due to one of the following defects: High frequency electrotome, Transformer, Defibrillator, Wireless LAN equipment, Medical lasers, Scanners, Cauterizing guns, Computers, Monitors, Fans, Gel warmers, Microwave ovens, Light dimmers, Portable phones

The presence of a broadcast station or broadcast van may also cause interference.
If you find strong interference shows on the screen, please check the sources.

26. **Electromagnetic Compatibility (EMC)**

Operating the sensor in close proximity to sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

27. Do not modify this equipment without authorization of the manufacturer.
28. The system is not serviced or maintained while in use with the patient.

1.3.2 General Cautions

CAUTION

1. Before use, you must make sure that there is no visible evidence of damage on the equipment, cables and probes, which may affect patient safety or diagnostic capability. The recommended inspection interval is once per week or less. If damage is evident, replacement is recommended before use.
2. If the power cord of the system is missing, damaged or not provided, please purchase the power cord meeting the specification requirements for the original one and complying with the local regulations.
3. The device and accessories are to be disposed of according to local regulations. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.
4. Please use the standard power cord as the input line of the network power supply for the adapter to reduce risk.
5. No user serviceable parts are inside the system. All repairs on the system must be performed by Fussen certified service personnel.

NOTE

To avoid damaging the system, DO NOT use it in environment as below:

1. Locations exposed to direct sunlight.
2. Locations subject to sudden changes in ambient temperature.
3. Dusty locations.
4. Locations subject to vibration.
5. Locations near heat sources.
6. Locations with high humidity.

1.4 List of Symbols

	Caution
	Follow Instructions for Use
	**Type BF Device** The sensor is a Type BF device.
	Recycle
P/N	Part Number
SN	Serial Number
	Date of Manufacture
	Manufacturer
CE 0123	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
EC REP	Authorized Representative in the European Community
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life

2 About the Manual

2.1 Application of the Manual

The manual mainly introduces functions of the system and the way to operate it.

2.2 Applicable Object

The manual is applicable to clinical professionals and other authorized users.

2.3 Legend and Name

All legends provided in the manual are just for examples.

All names shown in examples and legends are imaginary. It is coincidence if somebody happens to have the same name with that in the manual.

3 Product information

Operation Temperature: 5℃ ~ 40℃

Relative Humidity: ≤80% (Non-condensed)

Atmospheric Pressure: 700~1060 mbar (hPa)

Power Supply: DC: 5V±5%

Power Consumption: 350mW

Anti-electroshock degree: BF

Harmful Ingress of Water proof degree: IP64

4 Overview

Digital intraoral x-ray imaging system is an intraoral digital sensor and an image acquisition software used with an intraoral X-Ray generator to capture digital images of dentition and the surrounding skeletal structures. The sensor is connected directly to a PC.

You must have a dedicated Computer with a 32-bit or 64-bit Windows operating system and have at least one High-speed USB port available. The computer requirements are listed in ORFC Software User Manual.

Image capture and management (ORFC) software must be installed on all computers that will host the sensors. The performance of that software is affected by the amount of RAM and storage memory available to the system for acquisition, displaying, storing, and printing digital X-Ray images. The recommended requirements are listed as a guideline only.

NOTE

Be aware that the patient volume, and the specific demands of your practice, may require adjusting these guidelines accordingly. The system requirements of other programs operating on the same computer or network may affect these guidelines as well.

5 Installation and Exit

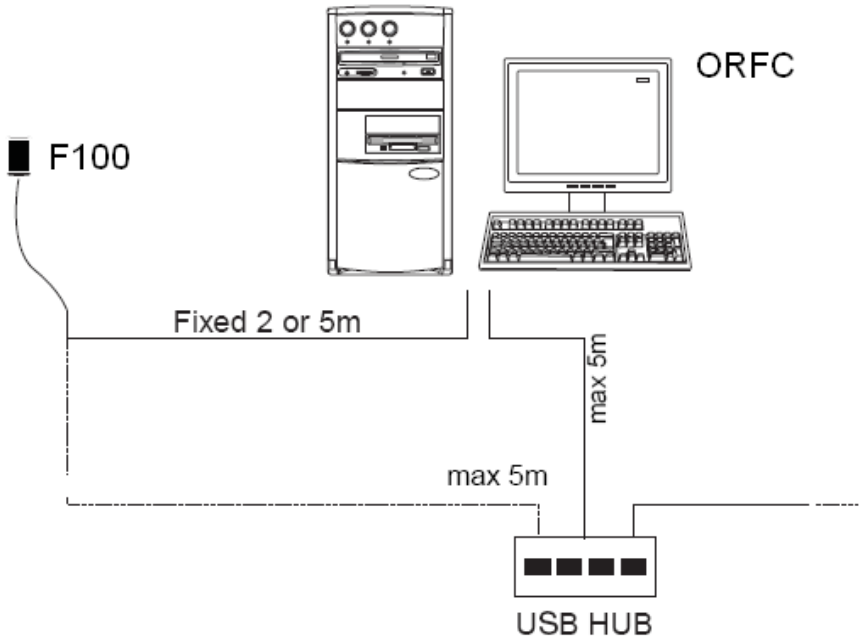
5.1 Installation

First, pull USB connect of Sensor into PC USB 2.0 port

NOTE

1. The USB calbe must be connected to USB sockers only. Do not connect the cables to any other equipment.

2. If the distance between the SENSOR and the PC exceeds 5M a HUB must be used.



Then start ORFC console, the software operating guide refer to the **Software User Manual**.

5.2 EXIT

1、Close ORFC console

2、Pull out F100 from computer USB port

6 Understanding the Imaging Chain

The imaging chain consists of the following components:

- Sensor
- X-ray generator
- Timer
- Computer and monitor

6.1 Sensor

.

The sensor is radio-sensitive.
The back of the sensor, non-reactive to x-rays, is rounded corner and contains the cable attachment.
Applied part is the sensor. In the operating environment of 40℃, the highest surface temperature of the sensor may reach the 42℃.

size 1, universal, sensor—Use for regular periapical and retro-coronary procedures.

The sensor is connected to the computer with USB 2.0 connector. You do not need to start the ORFC Software before you connect the sensor. However, you can acquire the image only in the imaging module. You can disconnect the sensor with the power on, but do not disconnect the sensor when you are acquiring an image. This can damage the sensor.

6.2 X-ray Generator

The x-ray generator has a significant impact on image quality. Due to its high sensitivity and capacity to store an enormous quantity of information, the sensor requires high-energy rays generated over very short time periods. This way, the images are formed by a maximum number of gray levels and you can process the images digitally to assist in extracting the clinical information.

WARNING

The power of a generator decreases over time. Have the generator inspected annually to determine any difference between its nominal and effective power.

As a general rule, the sensor is compatible with all generators provided the generator meets the current standard of intraoral radiology. You can use a high-frequency or conventional generator. The generator must operate with a voltage of 60 to 70kV.

The generator head must have a long cone with a focal point / film distance of at least 20 cm, to concentrate the x-rays toward the sensor. Select a mechanism that supports the generator and provides stability to avoid any motion blurring due to vibration of the x-ray source.

WARNING

The sensor is not compatible with generators of lesser specifications.

6.3 Timer

Use the timer to control exposure times. The selected exposure time does not exactly represent the dose of x-rays output by the generator since the variations in the mains current has not been taken into consideration. Use a digital timer to compensate for current variations in conventional generators.

Remember that the image quality for short exposures is linked to the use of the physical synchronization function of the sensor and the timer, in particular with the very high-frequency Fussen intraoral x-ray units.

6.4 Computer and Monitor

Place the computer and its monitor in or close to the operating area, to ensure the visual field of the practitioner. Provide visual access for the patient, to encourage communication.

Use a monitor with proper technical display characteristics for the visualization of radiological images. Select and set up the monitor according to the procedure described in the installation guide for the sensor. Position the monitor to avoid direct light or reflections that could affect the reading of the clinical information.

Caution

A poor monitor setting or a poor quality monitor can cause diagnostic errors due to the inability of the equipment to display the image properly.

6.5 Adjusting Exposure Time

As in conventional radiology, the exposure time depends on the following:

- Generator type
- Patient's morphology
- Tooth which is x-rayed

Table 2–1 provides you guidelines of exposure times for an average generator at 70kV and 4mA. These are approximate values.

Adjust the values for your generator:

- If the images are displayed too dark, reduce the exposure settings.

- If the images are displayed too light, increase the exposure settings.

Add the values for corrections in the second column of Table 6–1.

Table 6–1 Sensor Exposure Times

Acquisition Mode	High Resolution	
	Seconds	Correction
Upper incisor/canine	0.18	
Upper premolar	0.24	
Upper molar	0.40	
Lower incisor/ canine	0.12	
Lower premolar	0.18	
Lower molar	0.24	

Note

The exposure times in Table 6–1 are suggested times. Over time and with experience, you can identify the settings specific to the configuration in your practice.

Operating tips and recommended exposure times are given for an average case, representing an adult patient weighing approximately 80 kg. The distance between the sensor and the generator's focal point is approximately 23 cm. The exposure times varies according to the patient and the angle used to take the x-ray. Increase the dose proportionally to the square of the distance.

Note

The programmed time varies as the square of the distance. If the distance sensor / focal point of the generator raised, increase the dose.

6.6 Acquiring a Good Image

To obtain a good image in digital radiology, follow the rules that apply to classic radiology. The same anatomy limitations determine the positioning of the sensor in the mouth. You may require time to adapt to the new dimensions of the sensor.

6.6.1 Preparing the Sensor

To ensure maximum hygiene, cover the sensor with a disposable protective sheath prior to using the sensor.
To prevent cross-contamination, use a new hygienic barrier for each new patient. For optimum performance, use protective sheaths specifically designed for the size of sensor.

Note

For the additional instructions on hygiene, see “Disinfecting the Sensor and Maintaining Hygiene”

6.6.2 Positioning the Sensor

An X-ray image sensor is positioned in the patient’s mouth just like intraoral film. Figure 6–1 shows a positioning example.

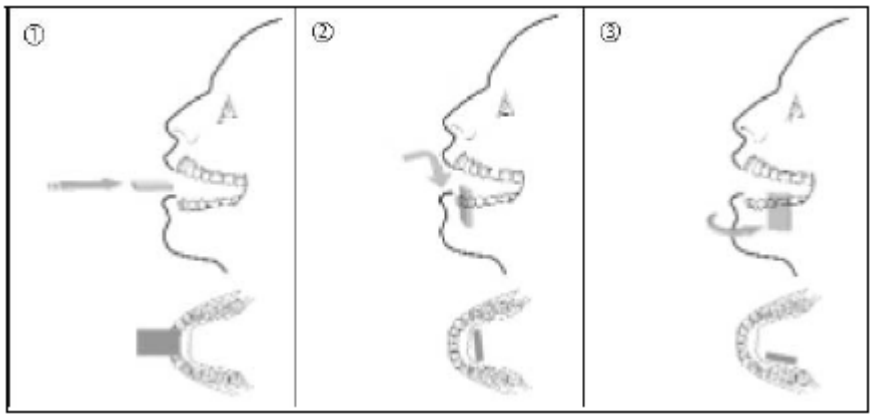


Figure 6–1 Positioning Example

6.6.2.1 Positioning the Sensor for a Mandibular Image

To position the sensor for a mandibular image, follow these steps:
1. Have the patient draw the tongue towards the back of the mouth. Insert the sensor holding it horizontally.

2. Then turn the sensor downward to place it in a vertical position.

3. Center the sensor on the targeted tooth.

For premolars and incisors, move the sensor towards the center of the mouth by compressing the tongue when the mouth closes to relax the muscles. The rigidity of the sensor and the positioning system aids in obtaining the image.

6.6.2.2 Positioning the Sensor for a Maxillary Image

To position the sensor for a maxillary image, follow these steps:

1. Insert the sensor, maintaining it horizontally.

2. Turn the sensor upward so that it is vertical or parallel to the axis of the target tooth.

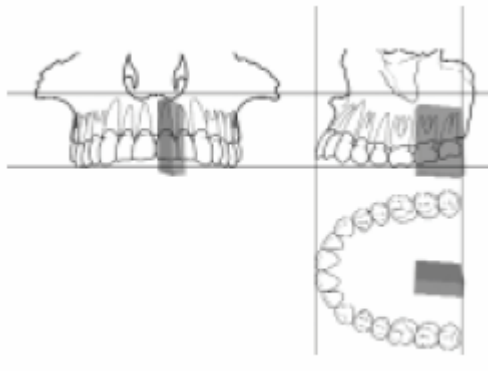
3. Center the sensor on the tooth to be x-rayed by sliding it distally.

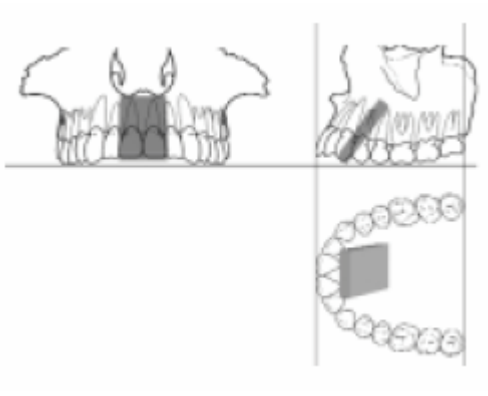
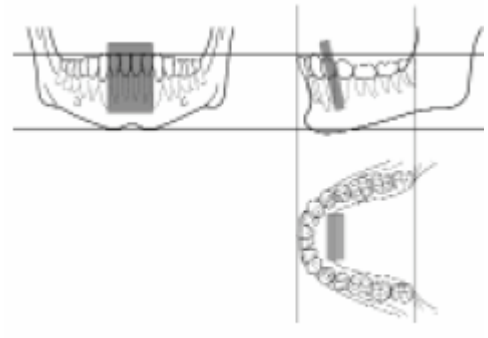
6.6.2.3 Using the Different Positioning Systems

The sensor is positioned with the same principles of the conventional radiography. Rigidity of sensor can avoid X-ray imaging distortion easily.
You can use different systems for positioning intraoral sensor. However, none of them can fulfill all of its functions. How you position the sensor is dictated by the morphology of the patient, the habits of the practitioner and the information you need, rather than the positioner itself. You can switch from the paralleling technique to the bisecting technique, from holding the sensor with the finger to use the holders.

Table 6–2 describes examples of positioning.

Table 6–2 Positioning Examples

Example	Description
	**Upper posterior region** Use the roundness of the palate to place the sensor to frame the apical area. Use Rinn* type positioners for paralleling technique.

	**Maxillary Anterior region** Use a bisecting technique. Have the patient hold the sensor against the tooth with a finger. For the paralleling technique, move the lower part of the sensor away from the incisive edge to place it parallel to the real axis of the teeth.
	**Lower Anterior Region** For a narrow mouth, move the sensor back parallel to the real axis of the teeth while pushing back the tongue slightly. Use the blunt edges of the sensor to depress the floor of the mouth to better frame the apical area.

(*) This product is recommended for use Rinn film holder is DENSPLY company's production of the following products:

Code	Model
559900	XCP-DS FIT™ Hygiene Kit
559908	XCP-DS FIT™ Endo Kit
559909	XCP-DS FIT™ Hygiene Kit plus Endodontic Holders
550771	XCP-ORA® Arm & Ring, 1-pk
550772	XCP-ORA® Arm & Ring, 2-pk
550773	XCP-ORA® Ring only, 1-pk
550774	XCP-ORA® Arm only, 1-pk
550598	XCP-DS® Endo Ring, 1-pk
50597	XCP-DS® Endo Arm, 1-pk
559901	XCP-DS FIT™ Anterior Biteblock, 2-pk
559902	XCP-DS FIT™ Posterior Biteblock, 2-pk
559903	XCP-DS FIT™ H Bitewing Biteblock, 2-pk
559904	XCP-DS FIT™ V Bitewing Biteblock, 2-pk

559905	XCP-DS FIT™ Endo Biteblock, 2-pk

7 Software operating Guide

About the software operating guide refer to the **software manual**.

8 Disinfecting and Maintaining the Sensor

8.1 Disinfecting the Sensor and Maintaining Hygiene

Carefully follow the procedure detailed earlier in this manual on how to prepare the sensor to ensure maximum hygienic safety for the patient.

Note

Our sensors are supplied non-sterile.

To disinfect the sensor and maintain proper hygiene, follow these guidelines:

- Use a new hygienic barrier for each new patient. The barrier must be biocompatible following the standard ISO 10993-1.
- When selecting a disinfectant product, check the list with the product manufacturer's information carefully.
- Do not clean the sensor or cable with abrasive tools.
- Do not use disinfectants that contain bleach or alcohol.
- The sensor cable can be soaked in a disinfecting solution as long as there is no mechanical damage to the cable. If mechanical damage is recognized, consult with Fussen technical support before attempting to immerse the cable.
- Thoroughly disinfect the sensor after each patient. Remove the hygienic protective sheath and thoroughly clean the sensor with a disinfecting wipe.
- Use only cold disinfecting products that are authorized by local dental regulatory agencies.

- Follow the manufacturer's recommendations for safety precautions when using the disinfectant product.
- Before the use of sensor, clean the sensor and the first centimeters of the cable by using a disinfecting cloth. Wipe down the sensor with a sterile solution and keep the sensor off of the floor at all times.

Preferred disinfecting liquids:

DENTASEPT (trademark of ANIOS Laboratories)

Prohibiting the use of

Alcohols (Isopropyl Alcohol, Methanol)
SEKUSID-N (trademark of Ecolab Paragerm Laboratories)
SEKUSEPT Easy (trademark of Ecolab Paragerm Laboratories)
FD333 (trademark of DURR Dental Laboratories)
FD332 (trademark of DURR Dental Laboratories)

Caution

1. Do not place the sensor in an autoclave. This can damage the system.

2. Do not immerse the connector and the sensor.

Note

Immerse part of the cable to guarantee a good disinfection.

8.2 Cleaning the Cable

Clean the cable carefully by using a disinfecting wipe.
When cleaning the cable, with one hand holding the sensor, the other hand has been wiped from the end of the sensor over the first twelve inches of the cable without pulling on the cable insulation. Slide the wipe without force, pinching the cable between the fingers with minimal pressure.

8.3 Storing the Sensor After Use

It is strongly recommended that you store the sensor in its case at the end of the day to prevent it from falling or from coming into contact with abrasive cleaning products.

8.4 Maintaining the Sensor

WARNING

Follow these guidelines to prevent damage to the sensor.

In order to extend the life of the sensor, do the following:

- Do not place the sensor in a sterilizer or autoclave.
- Do not pull on the cable, even when removing the disposable protective sheath.
- Do not walk on or roll objects over the cable.
- Do not request the patient to bite on the sensor or the cable.
- Do not disconnect the sensor during the 90-second delay, in non-synchronized mode, or during acquisition.
- Do not force, bend, or pull the cable at the sensor side.
- Do not immerse the sensor.

8.5 Preventing Electrostatic Discharge

To prevent electrostatic discharge, do the following:

- When the sensor is not connected, store it in its case.
- Do not touch the monitor's screen and the sensor simultaneously. This can result in serious damage to the sensor.
- Do not touch the contact points of the USB connector of the sensor.

8.6 Protecting Computer Data

Back up the database daily on several high capacity magnetic media, streamer, ZIP, DAT, used alternately.
Ask for advice from your computer dealer. Store the copies in a secure location.

9 Maintenance

You should be familiar with all the operation methods of this system. It is strongly recommended to understand the whole operation process before use it.

F100 digital intraoral x-ray imaging system just needs simple maintenance during the operation process. But only the right operation method can guarantee durable and stable working. As a result, you must comply with the notice and maintenance presented by the manufacturer strictly.

WARNING

Turn off the power before cleaning.

CAUTION

1. Avoid pouring liquid on the equipment while cleaning

2. Never place the sensor in an autoclave. This can damage the system.

3. Never immerse the connector located on the other end of the cable, nor the sensor.

4. Immerse part of the cable to guarantee a good disinfection. Do not immerse the sensor.

Maintenance of the Main Unit and the Monitor

1) Keep the main unit and the monitor clean. The main unit case can be cleaned with a soft cloth dampened with water. If necessary, use a mild detergent but carefully remove any residue. Use water very sparingly to prevent liquid from seeping into the equipment.

2) The main unit and the monitor should be placed in a dry and well-ventilated place. Avoid placing them in a dusty and humid environment. The air path for cooling the system should be kept well ventilated.

Maintenance of the CD

1) Do not bend or press the CD.

2) Clean the CD with a disk cleaner. Do not use organic solvents such as acetone.

3) Do not handle the CD while smoking or eating.

4) Keep the CD away from direct sunlight and high temperature. Otherwise, the CD may become deformed.

5) Do not get the CD wet.

6） Do not touch the disk surface of the recorded side. If the surface becomes contaminated with any foreign substance such as fingerprints, reading data may be impossible.

10 Accessories

WARNING

Only accessories supplied by the manufacturer can be used. Or else, the performance cannot be guaranteed.

Table 1 Standard Accessory List

Accessory	Quantity
USB Cable	1
Installation CD	1
Sensor	1

Table 2 Optional Accessory List

Accessory	Quantity
Softdog	1
Computer	1

The F100 digital intraoral x-ray imaging system and accessories are available by contacting the manufacturer or your local distributor.

11 Warranty and Service

11.1 Warranty

Fussen warrants that Fussen's products meet the labeled specifications of the products and are free from defects in materials and workmanship that occur within warranty period. The warranty period begins on the date the products are shipped to distributors, for 1year.

The warranty is invalid in the case of:

a) Damage caused by handling during shipping.

b) Subsequent damage caused by improper use or maintenance.

c) Damage caused by alteration or repair by anyone not authorized by Fussen.

d) Damage caused by accidents.

e) Replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is found to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, Fussen will, at its discretion, repair or replace the defective part(s) free of charge. Fussen will not provide a substitute product for use when the defective product is repaired.

11.2 Contact us

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to Fussen service department at: info@fussenct.com.

Appendix A Specifications

Product Categories

Anti-electroshock degree	BF
Harmful Ingress of Water proof degree	IP64
Working mode	Continuous working
AP / APG equipment	Not category AP / APG equipment

Product Specifications

Weight	0.1KG
Size	39.5mm×26 mm±5%

Environmental Requirements

Temperature	
Operation	+5°C ~ +40°C
Transport and storage	-20°C ~ +55°C
Relative Humidity	
Operation	≤80%（Non-condensed）
Transport and storage	≤93%（Non-condensed）
Atmospheric Pressure	
Operation	700hPa ~ 1060hPa
Transport and storage	700hPa ~ 1060hPa
Electrical Specifications	DC 5V±5%
	Rated input power：350mW

Performance Parameters

Spacial Resolution	≥12LP/mm
Effective imaging area	30mm×20mm±5%
Blur, Artifacts	NO

Appendix B Troubleshooting Images

When troubleshooting problems that you may encounter with images, try to solve the problem by using the following instructions. If the problem persists, or if it is not outlined below, contact Fussen dental imaging support.

Table A–1 outlines troubleshooting methods for resolving most problems that you may encounter.

Table A–1 Troubleshooting Tips

Symptom	Cause and Corrective Action
After triggering the x-rays, no image is displayed.	● Make sure a patient record is open in imaging mode. ● If the system is not connected to the timer: Check that the Acquisition button is active, not grayed out. If the button is grayed out, check the connection of the sensor on the USB 2.0 port. The acquisition function was not activated, click on the Acquisition button. The button turns green or use the button on the remote control, take the X-ray image within 90 seconds. ● If the system is connected to the timer: Check the connection with the timer. Check that the hub is powered properly. Contact your dealer.
The image is pale and grainy.	● The exposure time is too short; increase it. The selected acquisition mode does not correspond to the x-ray dose used. ● The generator voltage is too low (<60 kV rms); have the generator checked. ● The generator is too far from the patient with respect to the selected dose. ● Check the monitor contrast and brightness settings and ensure there are no reflections on the screen.
The image is too dark.	● The exposure time is too high; lower it. ● The selected acquisition mode does not correspond to the

	x-ray dose used. ● Check the monitor settings (contrast and brightness) and ensure there are no reflections on the screen.
The image is blurred.	● Patient moved during exposure. ● Generator head was not stable. ● Use an image filter.
The image is white.	● Active face of sensor was not exposed to x-rays. ● X-ray dose is insufficient. ● Sensor is not connected, or is improperly connected. ● Ensure the generator is producing x-rays; have it checked by a certified technician.

Appendix C EMC Declaration

Guidance and manufacturer's declaration – electromagnetic immunity			
The F100 is intended for use in the electromagnetic environment specified below. The customer or the user of the F100 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the F100 requires continued operation during power mains interruptions, it is recommended that the F100 be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

EMC Declaration (Continued)

Guidance and manufacturer's declaration – electromagnetic immunity			
The F100 is intended for use in the electromagnetic environment specified below. The customer or the user of the F100 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the F100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** **d=1.2 √ P** d=1.2 **√ P** **80MHz to 800MHz** **d=2.3 √ P 800MHz to 2.5 GHz** where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the F100 is used exceeds the applicable RF compliance level above, the Medical F100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the F100.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

EMC Declaration (Continued)

Guidance and manufacturer's declaration – electromagnetic emissions		
The F100 is intended for use in the electromagnetic environment specified below. The customer or the user of the F100 should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The F100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The F100 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the Medical F100			
The F100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Medical F100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the F100 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	**0.12**	**0.12**	**0.23**
0,1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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